

§ 411.350 Scope of subpart.

(a) This subpart implements section 1877 of the Act, which generally prohibits a physician from making a referral under Medicare for clinical laboratory services to an entity with which the physician or a member of the physician's immediate family has a financial relationship.

(b) This subpart does not provide for exceptions or immunity from civil or criminal prosecution or other sanctions applicable under any State laws or under Federal law other than section 1877 of the Act. For example, although a particular arrangement involving a physician's financial relationship with an entity may not prohibit the physician from making referrals to the entity under this subpart, the arrangement may nevertheless violate another provision of the Act or other laws administered by HHS, the Federal Trade Commission, the Securities and Exchange Commission, the Internal Revenue Service, or any other Federal or State agency.

(c) This subpart requires, with some exceptions, that certain entities furnishing covered items or services under Part A or Part B report information concerning their ownership, investment, or compensation arrangements in the form, manner, and at the times specified by HCFA.

§ 411.351 Definitions.

As used in this subpart, unless the context indicates otherwise:

Clinical laboratory services means the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.

Compensation arrangement means any arrangement involving any remuneration, direct or indirect, between a phy-

sician (or a member of a physician's immediate family) and an entity.

Direct supervision means supervision by a physician who is present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed.

Employee means any individual who, under the usual common law rules that apply in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986), is considered to be employed by, or an employee of, an entity. (Application of these common law rules is discussed at 20 CFR 404.1007 and 26 CFR 31.3121(d)-1(c).)

Entity means a sole proprietorship, trust, corporation, partnership, foundation, not-for-profit corporation, or unincorporated association.

Fair market value means the value in arm's-length transactions, consistent with the general market value. With respect to rentals or leases, *fair market value* means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee.

Financial relationship refers to a direct or indirect relationship between a physician (or a member of a physician's immediate family) and an entity in which the physician or family member has—

(1) An ownership or investment interest that exists in the entity through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing laboratory services; or

(2) A compensation arrangement with the entity.

Group practice means a group of two or more physicians, legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association, that meets the following conditions: